

one aspect, the lipase is liver carboxylesterase-B1-like protein. In another aspect, the lipase is liver carboxylesterase-1-like protein.

[0016] In one aspect, the sample comprises a polysorbate excipient. In a specific aspect, the polysorbate excipient can be selected from polysorbate-20, polysorbate-60, polysorbate-80 or combinations thereof. In yet another specific aspect, the polysorbate excipient can be polysorbate-80.

[0017] In one aspect, the probe can be capable of being linked to a solid support. In a specific aspect, the solid support can be agarose beads or magnetic beads.

[0018] In one aspect, the probe can be attached to a solid support using a ligand. In a specific aspect, the ligand can be an indicator, biotin molecule, a modified biotin molecule, a nuclei, a sequence, an epitope tag, an electron poor molecule or an electron rich molecule.

[0019] In one exemplary embodiment, the disclosure provides a method of decreasing degradation of polysorbate in a sample, comprising contacting the sample including lipase and polysorbate with a probe, said probe capable of binding to the lipase to form a complex and separating the complex from the sample to thereby decrease degradation of polysorbate in the sample.

[0020] In one aspect, the lipase is liver carboxylesterase-B1-like protein. In another aspect, the lipase is liver carboxylesterase-1-like protein.

[0021] In one aspect, the sample can comprise a protein of interest. In one aspect, the sample can comprise a polysorbate excipient. In a specific aspect, the polysorbate excipient is selected from polysorbate-20, polysorbate-60, polysorbate-80 or combinations thereof. In yet another specific aspect, the polysorbate excipient is polysorbate-80.

[0022] In one aspect, the probe can be capable of being linked to a solid support. In a specific aspect, the solid support can be agarose beads or magnetic beads.

[0023] In one aspect, the probe can be attached to a solid support using a ligand. In a specific aspect, the ligand can be an indicator, biotin molecule, a modified biotin molecule, a nuclei, a sequence, an epitope tag, an electron poor molecule or an electron rich molecule.

[0024] In one exemplary embodiment, the disclosure provides a composition comprising a protein of interest purified from mammalian cells and a residual amount of liver carboxylesterase-B1-like protein. In one aspect, the residual amount of liver carboxylesterase-B1-like protein is less than about 5 ppm. In another aspect, the composition can further comprise a surfactant. In yet a further aspect, the surfactant can be a hydrophilic nonionic surfactant. In another aspect, the surfactant can be a sorbitan fatty acid ester. In a specific aspect, the surfactant can be a polysorbate. In another specific aspect, the concentration of the polysorbate in the composition can be about 0.01% w/v to about 0.2% w/v. In a further specific aspect, the surfactant can be a polysorbate 80. In one aspect, the mammalian cells can include a CHO cell.

[0025] In one aspect, the liver carboxylesterase-B1-like protein can cause degradation of polysorbate 80.

[0026] In one aspect, the composition can be a parenteral formulation.

[0027] In one aspect, the protein of interest can be a monoclonal antibody, a polyclonal antibody, a bispecific antibody, an antibody fragment, a fusion protein, or an

antibody-drug complex. In one aspect, the concentration of the protein of interest can be about 20 mg/mL to about 400 mg/mL.

[0028] In one aspect, the composition can further comprise one or more pharmaceutically acceptable excipients. In another aspect, the composition can further comprise a buffer selected from a group consisting of histidine buffer, citrate buffer, alginate buffer, and arginine buffer. In one aspect, the composition can further comprise a tonicity modifier. In yet another aspect, the composition can further comprise sodium phosphate.

[0029] In one exemplary embodiment, the disclosure provides a composition comprising a protein of interest purified from mammalian cells and a residual amount of liver carboxylesterase-1-like protein. In one aspect, the residual amount of liver carboxylesterase-1-like protein is less than about 5 ppm. In another aspect, the composition can further comprise a surfactant. In yet a further aspect, the surfactant can be a hydrophilic nonionic surfactant. In another aspect, the surfactant can be a sorbitan fatty acid ester. In a specific aspect, the surfactant can be a polysorbate. In another specific aspect, the concentration of the polysorbate in the composition can be about 0.01% w/v to about 0.2% w/v. In a further specific aspect, the surfactant can be a polysorbate 80. In one aspect, the mammalian cells can include a CHO cell.

[0030] In one aspect, the liver carboxylesterase-1-like protein can cause degradation of polysorbate 80.

[0031] In one aspect, the composition can be a parenteral formulation.

[0032] In one aspect, the protein of interest can be a monoclonal antibody, a polyclonal antibody, a bispecific antibody, an antibody fragment, a fusion protein, or an antibody-drug complex. In one aspect, the concentration of the protein of interest can be about 20 mg/mL to about 400 mg/mL.

[0033] In one aspect, the composition can further comprise one or more pharmaceutically acceptable excipients. In another aspect, the composition can further comprise a buffer selected from a group consisting of histidine buffer, citrate buffer, alginate buffer, and arginine buffer. In one aspect, the composition can further comprise a tonicity modifier. In yet another aspect, the composition can further comprise sodium phosphate.

[0034] In one exemplary embodiment, the disclosure provides a method of detecting a lipase in a sample. In one aspect, the lipases can be liver carboxylesterase-1-like protein or liver carboxylesterase-B1-like protein. In one aspect, the method of detecting a lipase in a sample can comprise contacting the sample with a serine hydrolase probe. In one aspect, the method of detecting a lipase in a sample can comprise contacting and incubating the sample with a serine hydrolase probe to form a complex of lipase and serine hydrolase probe. In a further aspect, the method of detecting a lipase in a sample can comprise filtering out the serine hydrolase probe that does not form the complex of lipase and serine hydrolase probe.

[0035] In one aspect, the method of detecting a lipase in a sample can further comprise contacting the contacting the sample with magnetic beads having an ability to bind to the serine hydrolase probe to such that magnetic beads are bound to the complex of lipase and serine hydrolase probe. The magnetic beads bound to the complex of lipase and